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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,509	10/28/2003	Gary G. Schwartz	SCZ-102	5435

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	PAPER NUMBER
1642	
MAIL DATE	DELIVERY MODE
04/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,509	SCHWARTZ ET AL.	
	Examiner	Art Unit	
	BRANDON J. FETTEROLF	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-22,24,26-29,31 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-22, 24, 26-29, 31 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/14/2008 has been entered.

Claims 20-22, 24, 26-29, 31 and 33 are currently pending and under consideration.

Rejections Withdrawn:

The rejection of Claims 20-38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicants amendments.

The rejection of claims 34-38 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of Applicants amendments.

The rejection of claims 20, 22-23, 25-27, 29-30 and 32-33 under 35 U.S.C. 102(b) as being anticipated by Raina et al. (Br. J. Cancer 1991; 63: 463-465, *of record*) is withdrawn in view of Applicants amendments to include the specific types of cancers to be inhibited.

New Rejections in view of Applicants amendments:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-22, 24, 26-29, 31 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Claims 20 and 27 have been amended to include the negative limitation that the analog, salt, or derivative thereof of 25-hydroxyvitamin D is "not hydroxylated at the 1-alpha position". However, a careful review of the specification and claims, as originally filed, do not appear to lend support for the negative limitation. In the instant case, any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20-22, 24, 26-29, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Getzenberg et al. (Urology 1997; 50: 999-1006, of record) in view of Haussler et al. (JAMA 1982; 247: 841-844, *of record*).

Getzenberg et al. teach a method of inhibiting prostate tumor and/or cancer growth in an animal, comprising administering 1,25-D3, e.g., calcitriol, and less-hypercalcemic analogues, Ro25-6760, to an animal (page 1003, Table II and IV).

Getzenberg et al. does not explicitly teach that the administration of 25-hydroxyvitamin D as the metabolic precursor.

Haussler et al. teach that while calcitriol is the most active natural metabolite of Vitamin D, analogs such as calcifediol (25-hydroxyvitamin D) are safe and effective alternative therapeutic agents to Vitamin D (abstract). Specifically, the reference teaches that calcifediol has become a useful alternative to Vitamin D because it is faster acting and assays for measuring its concentration are readily available such that its therapeutic levels can be easily monitored; and further, calcifediol has been shown to substitute for 1,25-D3, e.g., calcitriol, at receptor sites (page 843, 2nd column, *Calcifediol*).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute calcitriol as taught by Pence for 25-hydroxyvitamin D in view of Haussler et al. teachings that calcifediol, e.g., 25-hydroxyvitamin D, is recognized as a safe and effective alternative to Vitamin D. Moreover, one would have bee motivated because as taught by Haussler, calcifediol is faster acting than vitamin D and its therapeutic levels can be easily monitored by readily available techniques; and further, calcifediol has been shown to substitute for 1,25-D3, e.g., calcitriol, at receptor sites. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by administering 25-hydroxyvitamin D, one would achieve a safe and effective alternative to 1,25-D3, e.g., calcitriol, for the treatment of cancer.

In the instant case, it is noted that Applicants appeared to of responded to the previous rejection (see Remarks, page 4). However, a portion of this response appears to be missing (see page 4, middle paragraph). As such, it unclear what Applicants full response to the prior rejection was; and therefore, the partial response will not be commented on by the Examiner.

Therefore, No clam is allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,521,608 (2003, of record), which claims a method of treating in a subject a tumor that expresses a Vitamin D receptor, the method comprising administering a dose of a Vitamin D drug to raise the blood level of the Vitamin D drug, wherein the Vitamin D drug is 25-hydroxyvitamin D3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
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